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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,677	05/15/2002	Nicole Suci-Foca	58332-A-PCT-US/JPW/FHB	2458

7590 10/20/2004

John P White  
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New York, NY 10036

EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/018,677

**Applicant(s)**

SUCIU-FOCA ET AL.

**Examiner**

Michail A Belyavskyi

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Restriction*

1. Claims 1- 57 are pending.
2. The numbering of claims is not accordance with 37 C.F.R. 1.126. The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When claims are added, except when presented in accordance with 37 CFR 1.121(b), they must be renumbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 18 , second appearance on page 125 has been renumbered as claim 19. Misnumbered original claims 19-56 have been renumbered as claims 20-57.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted:

- I. Claims 1-3 are drawn to a method generating antigen specific allospecific human suppressor CD8+ CD28- T cells comprising stimulating T cells with allogeneic APCs.
- II. Claims 4 and 28-31 are drawn to a allospecific human suppressor CD8+ CD28- T cells and a vaccine comprising said T cells.
- III. Claims 5-7 are drawn to a method generating xenospecific human suppressor CD8+ CD28- T cells comprising stimulating T cells with xenogeneic APCs
- IV. Claims 8 and 32-33 are drawn to a xenospecific human suppressor CD8+ CD28- T cells and a vaccine comprising said T cells.
- V. Claims 9-10 are drawn to a method generating antigen specific allospecific human suppressor CD8+ CD28- T cells comprising stimulating T with APC pulsed with allopeptide.
- VI. Claim 11 is drawn to a allospecific human suppressor CD8+ CD28- T cells, obtained by stimulating T with APC pulsed with allopeptide.

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VII. Claims 12-13 are drawn to a method of determining whether a level of the immunosuppressant therapy given to a subject requires a reduction.

VIII. Claims 14-15 and 18 are drawn to a method of reducing the risk of rejection of an allograft in a subject comprising reintroducing the expanded T suppressor cells into the subject

IX. Claims 16 and 19 are drawn to a method of reducing the level of rejection of an allograft in a subject comprising administering to the subject T cells that primed with allogenic APC

X. Claims 17 and 20 are drawn to a method of reducing the level of rejection of an allograft in a subject comprising administering to the subject T cells that primed with APC pulsed with allopeptide

XI. Claims 21 and 22 are drawn to a method of preventing rejection of a xenograft, comprising reintroducing the expanded T suppressor cells into the subject

XII. Claim 23 is drawn to a method of preventing rejection of a xenograft, comprising administering to the subject T cells that primed with xenogeneic APC.

XIII. Claims 24 and 25 are drawn to a method of preventing autoimmune disease comprising reintroducing the expanded T suppressor cells into the subject

XIV. Claim 26 is drawn to a method of preventing autoimmune disease comprising administering to the subject T cells that primed with allogenic APC.

XV. Claims 27 is drawn to a method of preventing autoimmune disease comprising administering to the subject T cells that primed with APC pulsed with allopeptide.

XVI. Claims 34-36 and 38 are drawn to a method inducing anergic T helper cells which comprises incubating APC with allospecific Ts.

XVII. Claims 34-35 and 37 are drawn to a method inducing anergic T helper cells which comprises incubating APC with xenospecific Ts.

XVIII. Claims 39-41 and 43 are drawn to a method of generating a tolerogenic APC which comprises incubating APC with allospecific Ts.

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XIX. Claims 39-40 and 42 are drawn to a method of generating a tolerogenic APC which comprises incubating APC with xenospecific Ts.

XX. Claims 44-46 , 48 and 56 are drawn to a method of reducing the level of rejection of an allograft tissue or organ, comprising administering to the subject tolerogenic APC which overexpress MIR wherein said APC have been incubated with allospecific Ts.

XXI. Claims 44-45 and 47 are drawn to a method of reducing the level of rejection of an allograft tissue or organ, comprising administering to the subject tolerogenic APC which overexpress MIR wherein said APC have been incubated with axenospecific Ts.

XXII. Claims 49-51 and 53 are drawn to a method of suppressing an autoimmune disease comprising administering to the subject APC wherein said APC have been incubated with allospecific Ts.

XXIII. Claims 49, 50 and 52 are drawn to a method of suppressing an autoimmune disease comprising administering to the subject APC wherein said APC have been incubated with xenospecific Ts.

XXIV. Claims 54 and 55 are drawn to a method of suppressing an autoimmune disease comprising administering to the subject APC wherein said APC overexpressing MIR.

XXV. Claims 57 is drawn to a method of inducing tolerance to a xenograft tissue or organ in a subject comprising administering APC which overexpress MIR.

4. The inventions listed as Groups I-XXV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As was also found in the International Search Report, the Invention of Group I was found to have no special technical feature that defined the contribution over the prior art of Jiang et al. Jianj et al., teaches obtaining peripheral blood T cell from a subject and stimulating the cell in vitro multiple times with antigenic peptide to establish T cell line. Jiang et al., further teaches expansion of CD8+CD28- T cells for their suppressive effects. Jiang et al., further teaches that the finding reported in the reference have direct relevance to allo and xenogeneic reactivity as well as the treatment of autoimmune diseases.

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Since Applicant's Inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

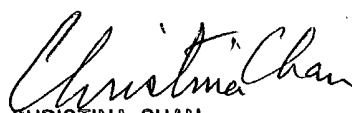
A telephone call was made to John White on 10/12/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskiy, Ph.D.  
Patent Examiner  
October 12, 2004

  
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